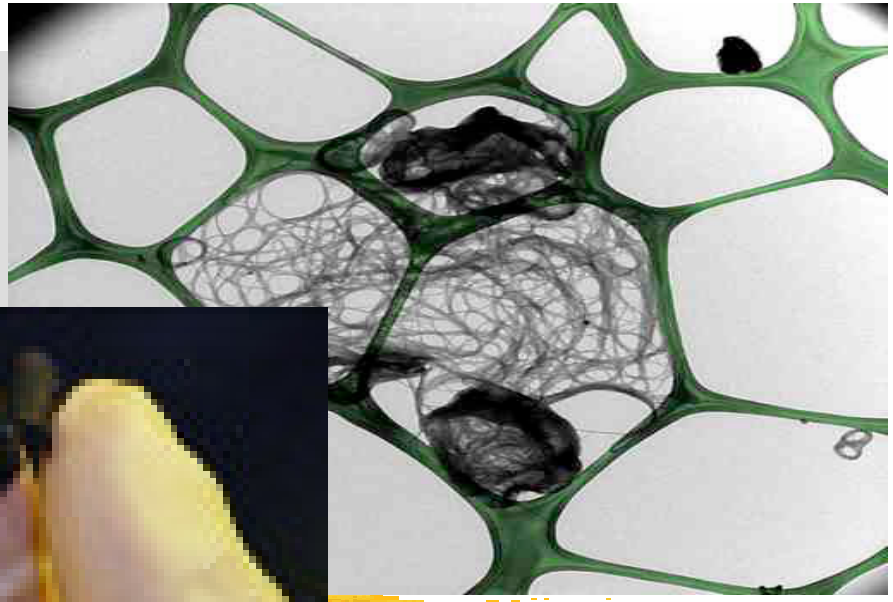
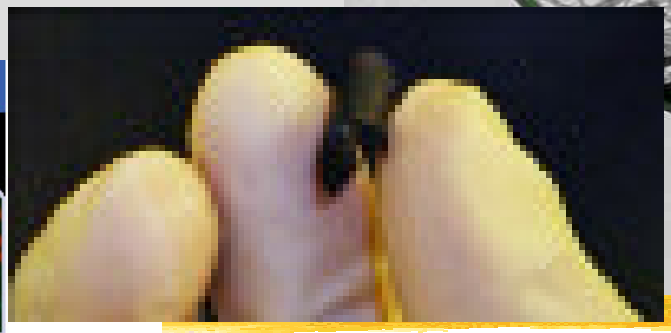
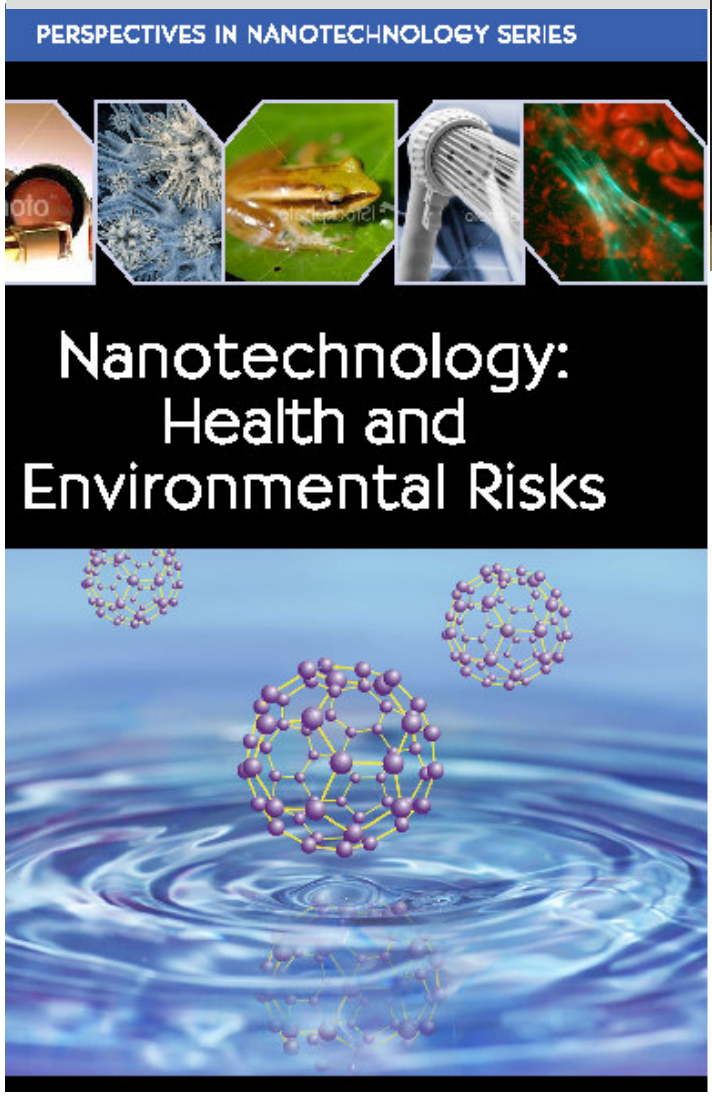
CLF Ventures







Systematic Approaches to Risk Assessment for Nanotechnology

Jo Anne Shatkin, Ph.D.
CLF Ventures

November 15, 2007

Overview

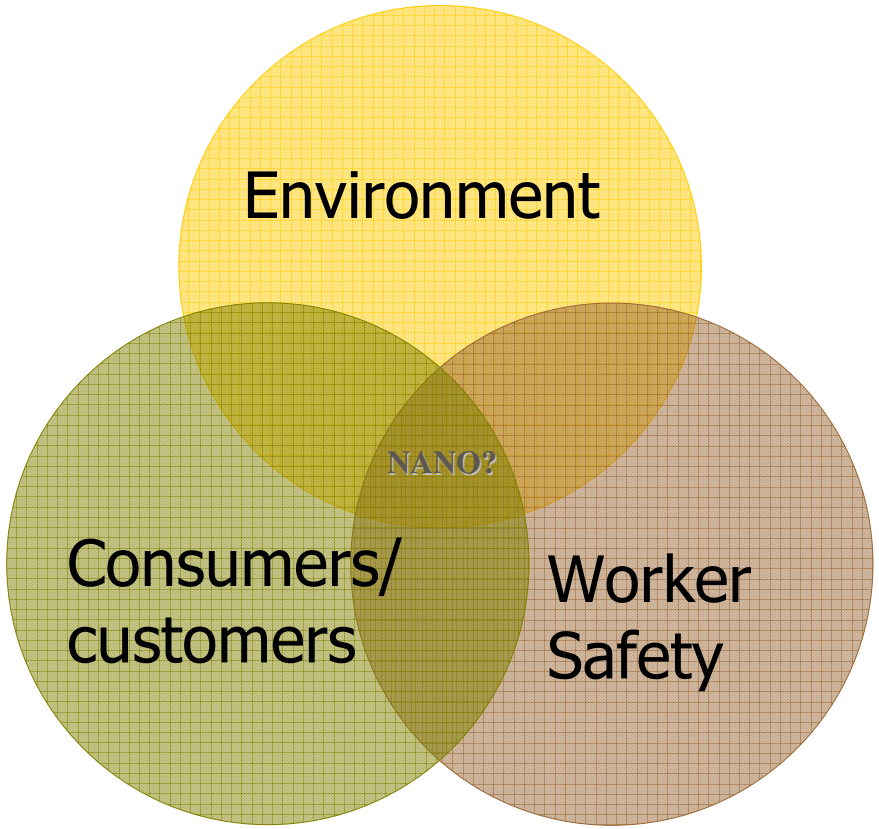
- **Risk assessment as an approach to managing emerging substances**
- **Adopting a life cycle approach in risk assessment**
- **Nano challenges to risk assessment**
- **Participatory risk assessment**

CLF Ventures leverages our relationships to launch environmentally responsible projects

- **Market Research and Analysis**
- **Building and managing stakeholder coalitions**
- **Access to Green Market Segments**
- **Establishment of Networks to Raise Capital**
- **Investment Fund Structuring**

Key Concerns about Nanotechnology Risk

- **Avoiding a "nano" legacy**
- **Uncertainty about health and environmental risks**
- **Lack of standards**
- **Hype – its unclear what is real**



Challenges Present Opportunities

- **Being proactive reduces risk**
  - Promotes environmentally sustainable technology development
  - If EHS concerns, need to address them, and develop approaches for assessment and management
- **Engineering materials provides flexibility to address EHS concerns up-front, if identified.**
- **Understanding risks provides a competitive edge in efficiently managing them**
  - When risks are anticipated, can plan for them, rather than reacting

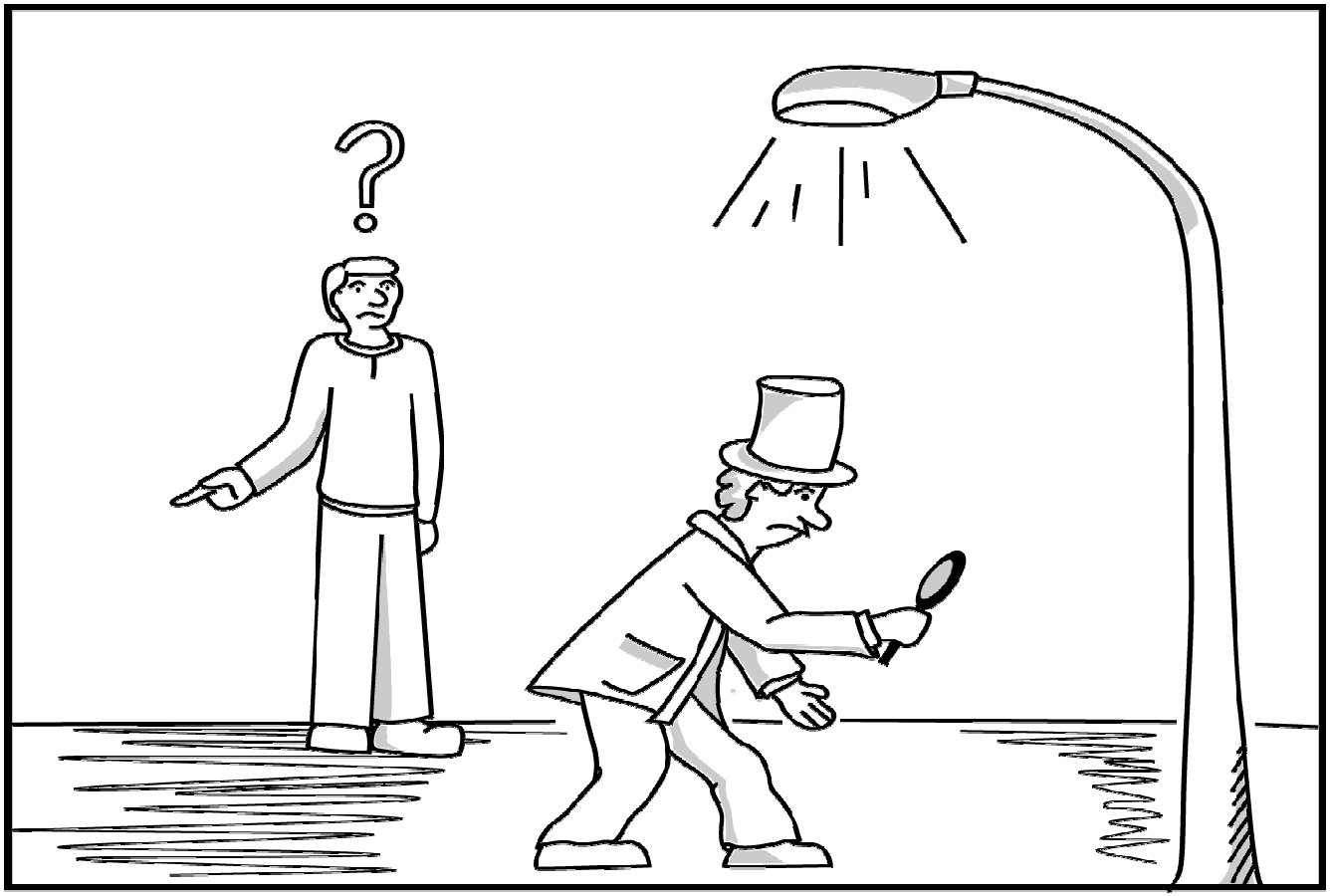
Understanding risks allows efficient management of them

- **Risk Assessment:**
  - Is increasingly part of regulatory structures
  - Allows decision making under uncertainty
  - Can address potential concerns throughout the life cycle of a product
  - Prioritizes research directions
  - Identifies areas for product innovation
  - Reduces potential for unforeseen impacts
  - Provides a tool box of approaches

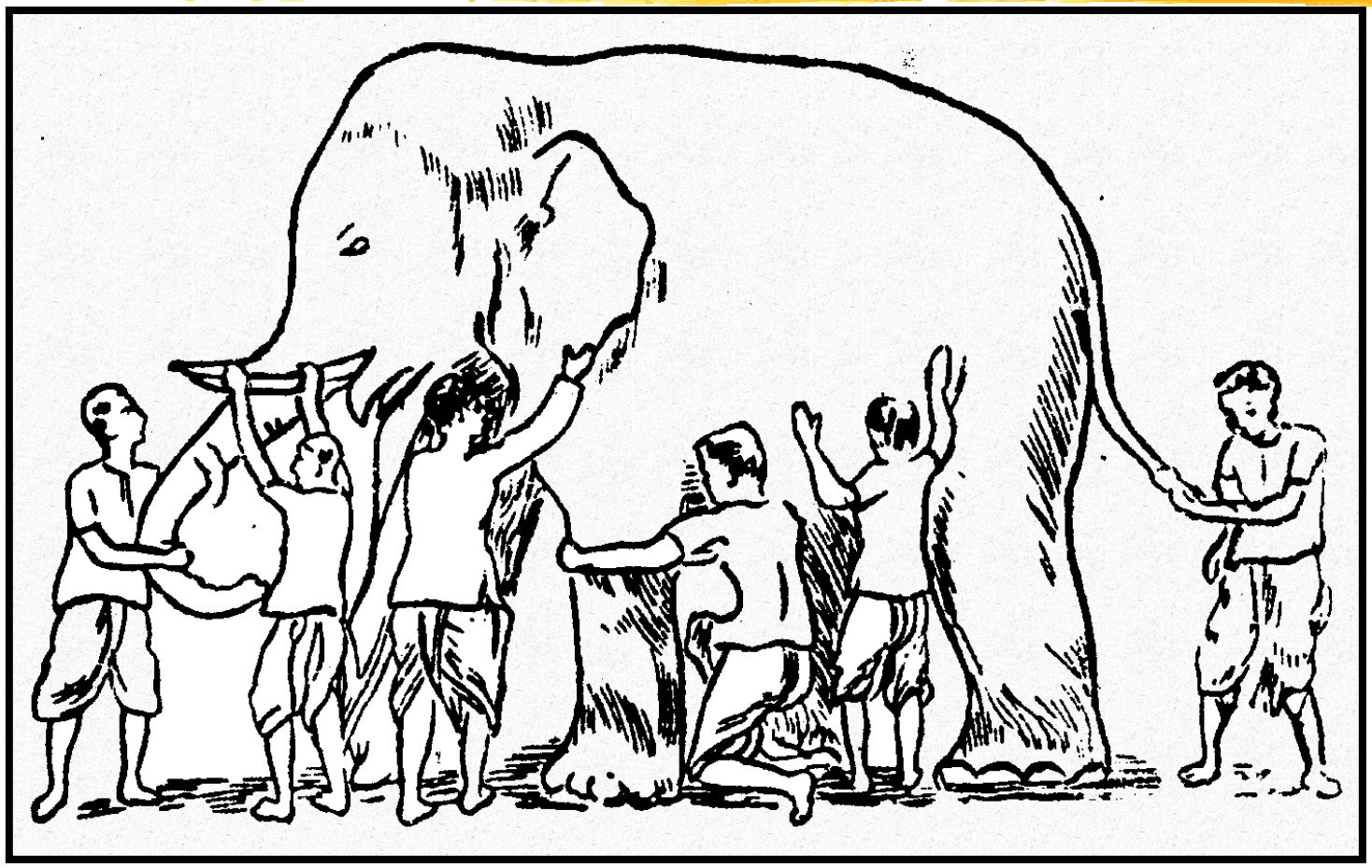
Differentiating Hazards from Risks

- **All materials are toxic at some concentration**
- **Risk = hazard * exposure probability**
- **There must be exposure or there to be a risk**

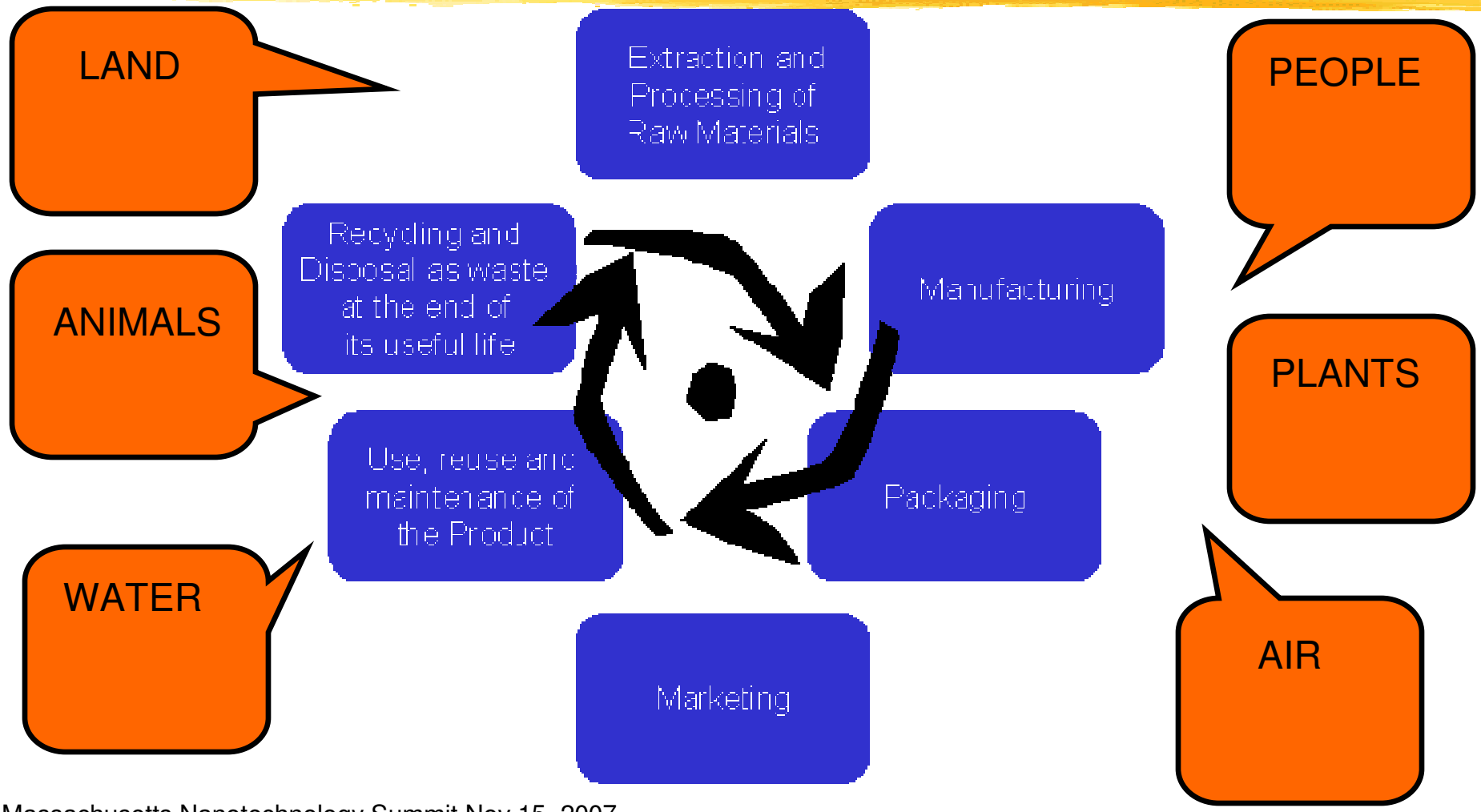
Searching for the Keys under the Street Light?



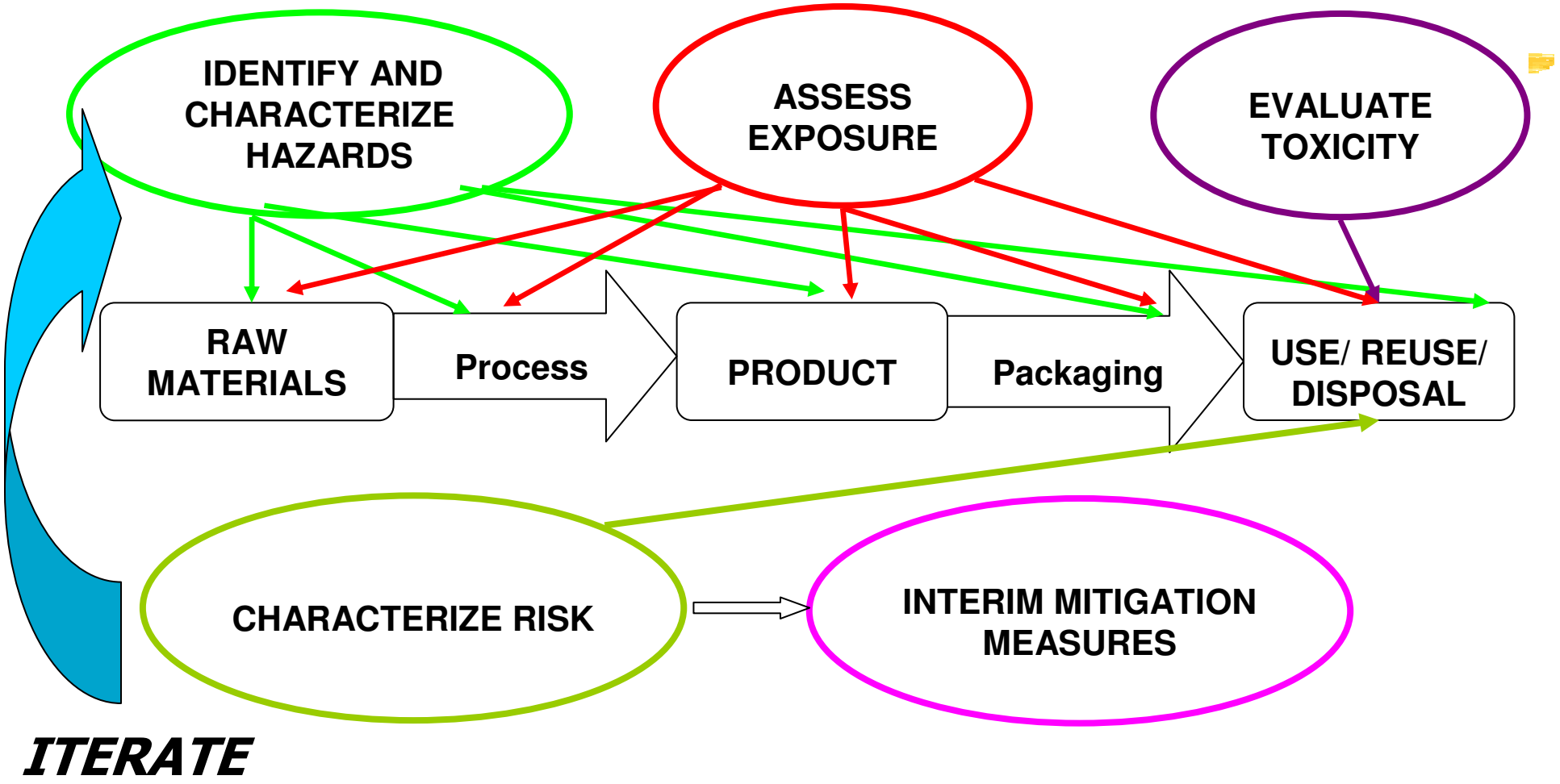
Look at the Big Picture!



Exposures During Product Life Cycle Stages



NANO LCRA, an Adaptive Screening Risk Assessment Framework for NM



Key Attributes of NANO LCRA Adaptive Risk Framework

- Identifies Potential for Hazard and **Exposure** at each step
- Focuses on exposure potential to streamline analysis
- Only evaluates toxicity and risk when exposure may occur
- Allows comparison of different NM products and processes
- Adaptive: easy to update when new information is available
- **Focuses and prioritizes risk management on key concerns**

Key Attributes of NANO LCRA Adaptive Risk Framework

- Initially, a streamlined analysis appropriate for early stage decisions
- Proactive approach for evaluating safety of novel materials
- Steps sequentially across processes through product lifecycle
- Applies to health and safety and environmental concerns
- Transparent decision framework

NANO LCRA framework

- Adaptive approach applies broadly to array of situations – not nano-specific
- Use as a screening tool to identify and prioritize health and environmental/ process issues
- Identifies key uncertainties
- Revisits early decisions with new information

NANO LCRA Features

- Affordable, easily implementable process even with few available data.
- Develops risk management practices for minimizing potential human health effects and environmental impacts.
- Applicable for NM research and development, product manufacturing, consumer applications, and evaluation of NM fate in the environment.
- Prioritizes future data needs.

Comprehensive Environmental Assessment (CEA)

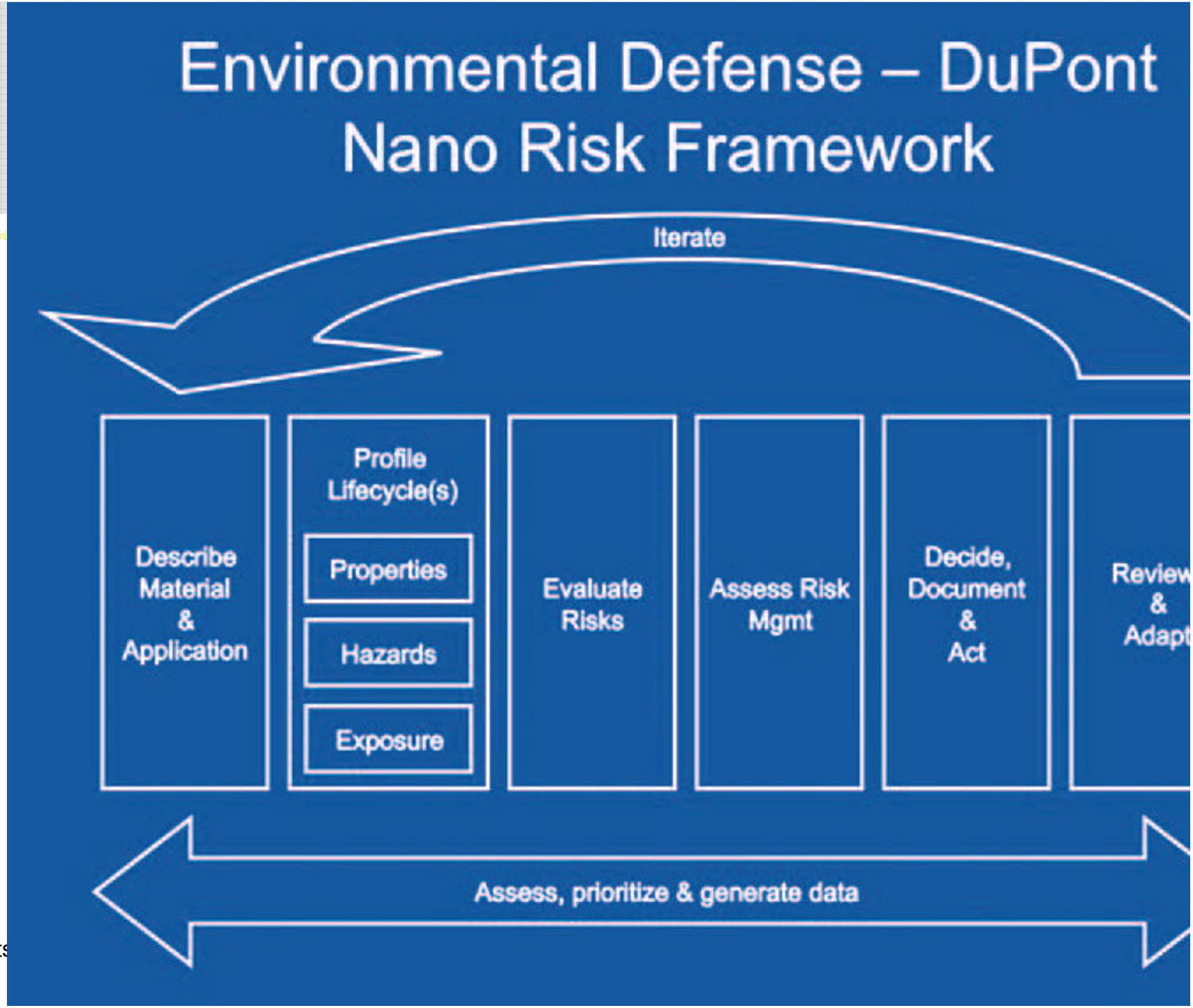
CEA = LC + RA

- Product Life Cycle framework
- Risk Assessment paradigm

See: Davis, J. M. "How to assess the risks of nanotechnology: learning from past experience" *J. Nanosci. Nanotechnol.* 7(2): 402-409, 2007

Comprehensive Environmental Assessment

Life Cycle Stages	Environment Pathways	Fate & Transport	Exposure	Effects
Feedstocks	Air	Primary contaminants	Inhalation	Eco-systems
Manufacture	Water		Ingestion	
Distribution	Soil	Secondary contaminants	Absorption	Human Health
Storage	Food chain		Injection	
Use				
Disposal				


Environmental Defense – DuPont
Nano Risk Framework
Iterate
Describe Material & Application
Profile Lifecycle(s)
Properties
Hazards
Exposure
Evaluate Risks
Assess Risk Mgmt
Decide, Document & Act
Review & Adapt
Assess, prioritize & generate data

Key Considerations for Assessing and Managing Nanotechnology Risks

- Everyone benefits from a **proactive** approach
- **Shared responsibility** – roles for government, developers, and investors
- **Participatory** approaches address the divergent views and expertise

Summary

- **Innovation is inherently risky**
- **The environmental, safety and health aspects of innovative materials are not well understood and are perceived as risky**
- **Companies, workers, customers plus the environment benefit from a proactive approach to identify and address potential risks early in the innovation cycle**
- **NANO LCRA Screening Level Risk Assessment is a useful tool for identifying and managing amidst uncertainty**

Risk Analysis is a Series of Steps:

- **Hazard Assessment**
  - *What* are we concerned about
- **Exposure Characterization: Develop a Conceptual Model**
  - *Who* could be exposed, *how* could exposure occur, *how much* could get from a source to an exposed person, and *how often*
- **Dose Response Evaluation**
  - What are the effects and at what exposure levels
- **Risk Assessment**
  - How do exposure levels relate to the effect levels
- **Risk Analysis**
  - What does this mean for health, safety, and the environment?

Issues in Hazard Characterization for Nanotechnology

- **How to define nanomaterials**
  - Distinguish engineered from other nanoparticles?
  - Are agglomerated or aggregated particles nano?
  - Is a composite material containing nanoparticles "nano"?
- **What are the appropriate measurement units?**

Issues in Exposure Assessment for Nanotechnology

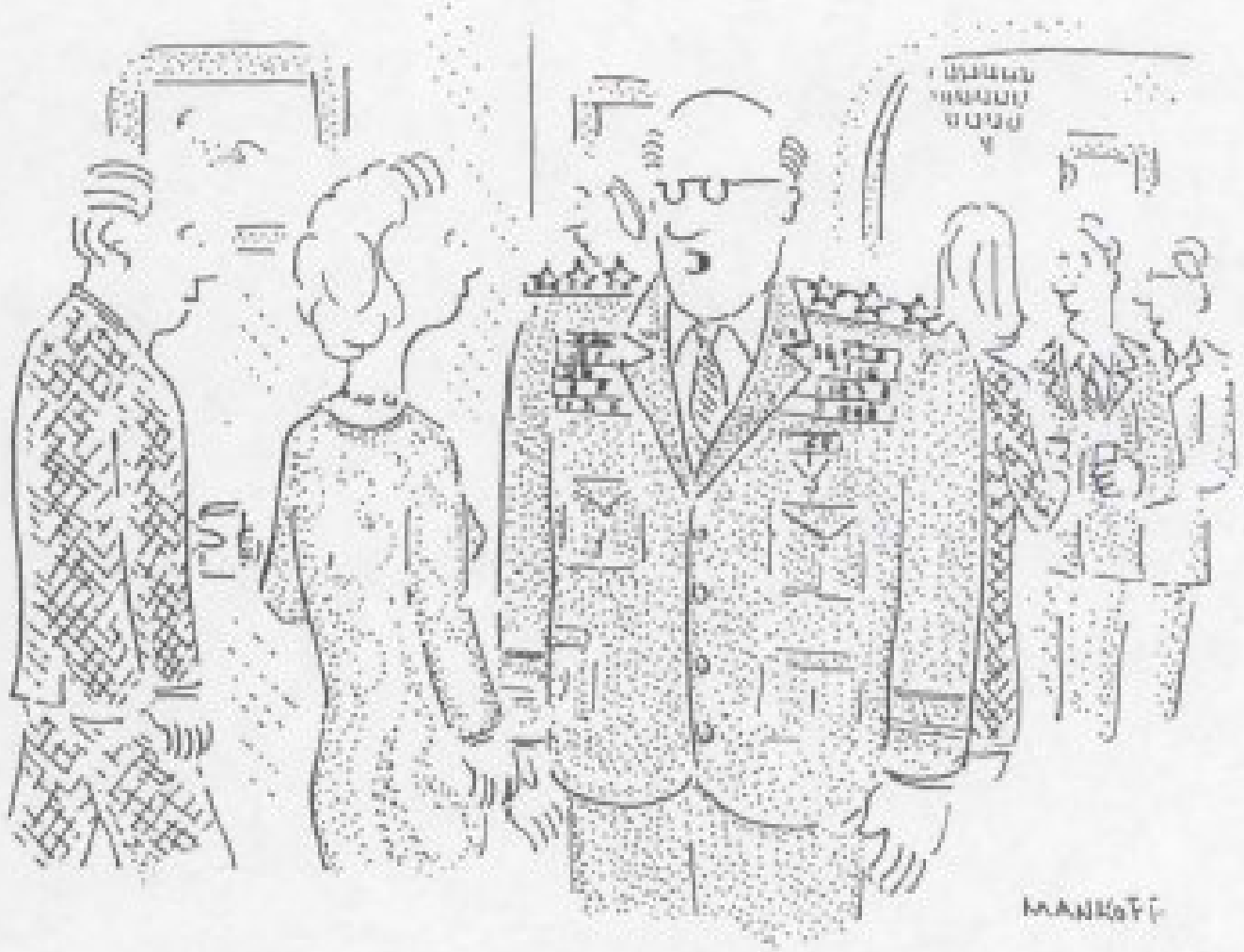
- **Need new ways to characterize exposure**
  - Mass may not be most useful measure
- **Limitations of available analytical techniques**
- **Will need low detection limits**
- **Also need to characterize "background" exposures**
- **Lack of information about transport and fate**

Dose Response for Nanotechnology

- Uncertainty in defining dose
- Different behavior of nanoparticles
- Difficulty in measuring responses
- Absorption, distribution, metabolism, excretion
- Diversity of materials and characteristics

Characterizing Risks of Nanomaterials

- **Currently – still much research to be done to quantify risks**
- **Available studies are comparative, e.g.**
  - Brunner et al. (2006) (comparative in vitro toxicity)
  - Sayes et al. (2004) (cytotoxicity of variously substituted C60 fullerenes)
  - Robichaud et al. (2005) (comparative risks of nanomanufacturing)



"Look, I'd like to avoid overkill, but not at the risk of underkill."

Source: K. Thompson, 2004.

Thank you for your attention

Lets Discuss these issues!

Society for Risk Analysis Emerging Nanoscale Materials Specialty Group (EMNMS)

SRA is 26 year old professional society with 2000 member international organization Interdisciplinary – breadth of expertise in risk specialty groups for disciplines

The Emerging Nanoscale Materials Specialty Group (EMNMS) aims to:

- **Facilitate the exchange of ideas and knowledge among practitioners, researchers, scholars, teachers, and others interested in risk analysis and emerging nanoscale materials.**
- **Encourage collaborative research on risk analysis and emerging nanoscale materials.**
- **Provide leadership and play an active role in advancing issues related to risk analysis and emerging nanoscale materials.**

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The Emerging Nanoscale Materials Specialty Group (EMNMS) SRANANO.ORG

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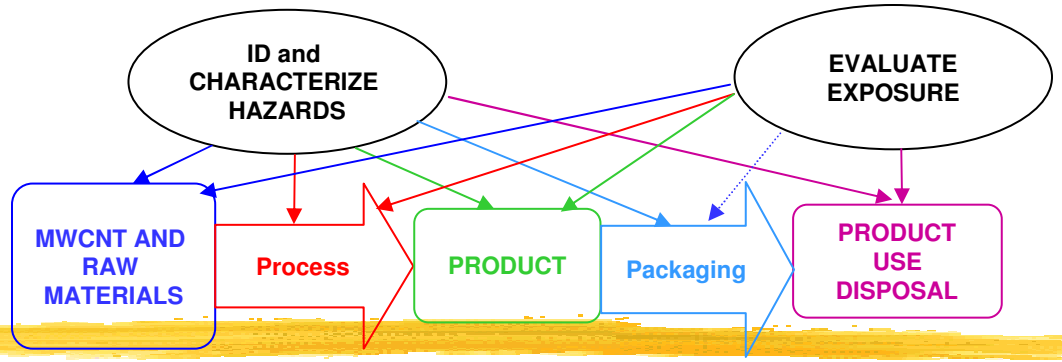
Upcoming SRA Nano Events

- **Society for Risk Analysis Annual Meeting**
  - San Antonio, Texas December 9-12 sra.org
  - The Influence of Questions: Case Studies of Nanotechnologies and Risk
  - Management of Nanomaterials: Current Developments and Tools
  - Nanotechnology Risk: Perceptions, Media Coverage and Public Acceptance
- **Nanotechnology workshops**
  - Introduction to Environmental and Health Aspects of Nanotechnology
  - SraNanoWorkshop.org
- **World Congress on Risk June 8-11 2008 Guadalajara**
  - Symposium on nanotechnology and risk

Nano LCRA Case Example 1 Company Using MWCNT to Manufacture Composites



Analysis

Hazard Identification

- MWCNT is Raw Material
- Inadequate use of PPE during NM mixture process
- Manual process for mixing in open environment
- Inadequate secondary containment in mixing area
- Improper disposal practices for NM wastes
- CNT in open air and water during product handling and packaging
- Use may cause direct contact with MWCNT

Exposure Assessment

- MWCNT in raw material is handled
- Liquid phase of process may release aerosols
- Potential for release of MWCNT from composite/product
- Normal Use and Disposal may release MWCNT

Recommendations

Inhalation and Dermal Exposures

- Install secondary containment in mixing area
- Spill containment procedures

Direct Contact Exposures

- Assess exposures during packaging and handling
- Assay composite to determine exposure potential

Environmental Exposures

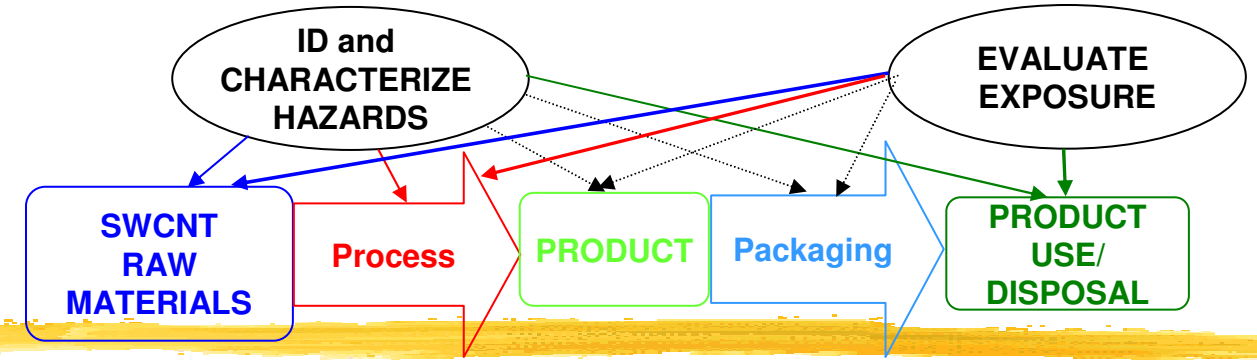
- Develop waste disposal practices

Toxicity

- Complete exposure assessment to identify material for toxicity study

NANO LCRA

Case Example 2 Company Producing SWCNT for Biomedical Product



Analysis

Hazard Identification

- Single walled carbon nanotubes released during process
- Improper disposal practices for NM wastes
  Product contains unbound CNT
- Trip and fall hazards in production area
- **Exposure Assessment**
- Material production process for SWCNT not enclosed
- Poor chemical hygiene practices increase exposure potential
- Final product for use in humans – potential dermal and internal exposure

Toxicity Assessment

- Test product toxicology in bioassays

Recommendations

Inhalation and Dermal Exposures

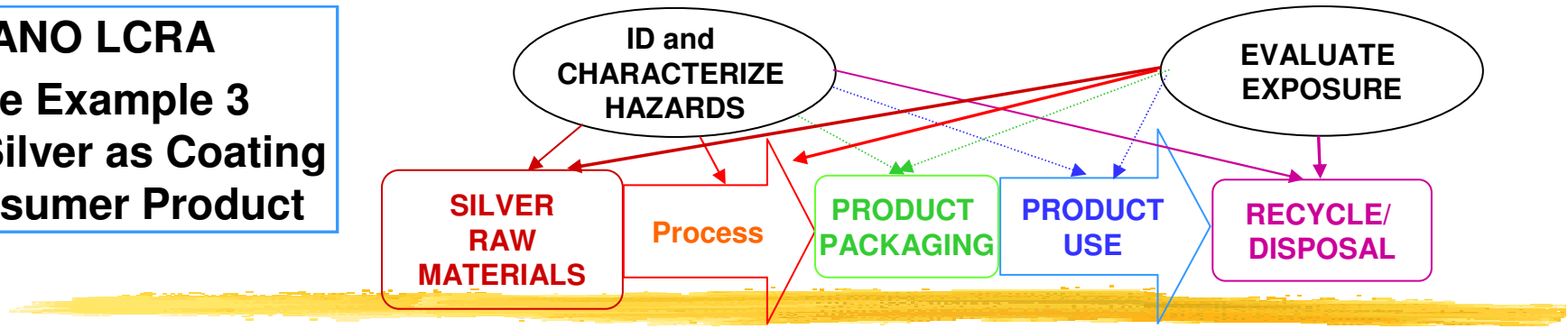
- Install secondary containment in SWCNT production area
- Contain process releases
- Provide PPE/training for handling SWCNT production materials
- Staff training on proper chemical storage procedures
- Develop disposal practices for NM wastes
- Shielding for explosion protection
- Remediate trip and fall hazards

Toxicity Assessment

- Material characterization
- Design protocol to assess toxicity of SWCNT product

NANO LCRA

Case Example 3
Nano Silver as Coating in Consumer Product



Analysis

Hazard Identification

- Release of silver during manufacturing
- Improper disposal practices for NM wastes
  Packaging step allows release of particles
- Product contains unbound silver particles
- Disposal may release silver to environment
- **Exposure Assessment**
- Worker exposure during production process
- Packaging into final product poorly controlled
- Final product includes human dermal contact exposure
- Recycling creates inadvertent exposure
- Environmental pathways unknown

Toxicity Assessment

- Potential dermal toxicity during use
- Unknown ecological fate and toxicity

Recommendations

Occupational hazards

- Install secondary containment in production area
- Develop disposal practices for NM wastes
- Contain packaging releases

Exposure Assessment

- Test dermal uptake in bioassays
- Conduct ecological fate evaluation

Toxicity Assessment

- Material characterization
- Assess toxicity of product
- *?? Conduct ecological tox studies ??*